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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,452	01/07/2002	David Wallach	WALLACH=1E	6011
1444	7590	09/22/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/036,452

Applicant(s)

WALLACH ET AL.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6/1/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED OFFICE ACTION**

Applicant's amendment filed on 01 June 2004 is acknowledged and entered. Following the amendment, claim 2 is canceled, and claims 7-9 are amended.

Currently, claims 1 and 3-9 are pending and under consideration.

#### **Withdrawal of Objections and Rejections:**

All objections and rejections of claim 2 are moot as the applicant has canceled the claim.

The nonstatutory double patenting rejection of claims 1 and 3-9 are withdrawn in view of the terminal disclaimer filed on 01 June 2004, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 5,695,953, and U.S. Patent No. 5,811,261, and in view of applicants argument. The terminal disclaimer has been recorded.

The rejection of claims 7-9 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

#### **Objections and Rejections under 35 U.S.C. 112:**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-9 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the last Office Action, paper No. 4, mailed on 01 December 2003, at pages 5-6.

Applicants argument filed on 01 June 2004 has been fully considered, but is not deemed persuasive for reasons below.

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At pages 8-9 of the response, applicants argue that this case is substantially identical to the rejection that has been appealed to the Court of Appeals for the Federal Circuit with respect to a related case from the laboratory of the present inventors, and a decision could be forthcoming at any time, that the present rejection should be withdrawn for the same reasons as presented in the brief before the Federal Circuit in *In re Wallach*. Applicants further argue that the disclosure of a protein by partial amino acid sequence and sufficient other characterizing data to present a full written description of that protein, is sufficient to provide written description of the genus of DNA which encode that protein, and that MPEP states that since the genetic code is widely known, a disclosure of an amino acid sequence would sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence. This argument is not persuasive because the example given by MPEP does not apply to the instant case as the present application merely discloses the amino acid sequence of a small portion (16 amino acid residues) of the entire molecule. Without the majority of the amino acid sequence of the polypeptide, there is no way for a skilled artisan to envision or predict the nucleic acid sequence encoding the polypeptide. Therefore, the present application does not provide sufficient written description for the claimed invention.

Further, the decision by the Federal Circuit in *In re Wallach* has been issued, and the Court clearly states:

Without the approximately 95% of the amino acid sequence that Appellants did not disclose, we cannot say that the DNA molecules claimed in the '129 application have been described. ... Appellants have not provided any evidence that the full amino acid sequence of a protein can be deduced from a partial sequence and the limited additional physical characteristics that they have identified. ... Until Appellant obtained the complete amino acid sequence of TBP-II, they had no more than a wish to know the identity of the DNA encoding it.

Therefore, for the reasons above, the written description rejection of claims 1 and 3-9 under 35 U.S.C. 112, first paragraph, is maintained.

**Conclusion:**

No claim is allowed.

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**Advisory Information:**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

  
LORRAINE SPECTOR  
PRIMARY EXAMINER

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
9/8/04